REMARKS

I. Status of Claims

Claims 1-28 are pending in this application.

In the present Amendment, paragraph [007] of the specification has been amended to correct a clear transposition error. Further, claims 1-7, 9-15, 17-23, and 28 have been amended. Support for the amendments can be found in the originally-filed specification and claims.

Specifically, in claims 1, 9, and 17, two additional provisos are added, which do not constitute new matter for at least the following reason.

"It is for the inventor to decide what *bounds* of protection he will seek." *In re Johnson*, 194 USPQ 187, 196 (CCPA 1977) (emphasis in original). In *In re Johnson*, the appellants amended claim 1 by adding provisos excluding certain species from the genus as originally claimed. *Johnson*, 194 USPQ, at 191. The court held that a limitation provisoing out the members of a genus originally described in the specification can be sufficiently supported by the original specification that taught the entire genus, because the "specification, having described the whole, necessarily described the part remaining." *Id.* at 196. Therefore, the appellants "are not creating an 'artificial subgenus' or claiming 'new matter.'" *Id.*

Similar to *Johnson*, the provisos added in claims 1, 9, and 17 of the present invention limit rather than expand the scope of the invention, by excluding certain species of the compound of formula (I) that are disclosed in the originally-filed specification. Therefore, as the court explained in *In re Johnson*, such an amendment

has sufficient support in the originally-filed application and does not introduce new matter.

In claims 7, 15, and 23, substituent "trifluoromethyl" for R is added, which does not constitute new matter, because the substituent "trifluoromethyl" for R is disclosed in paragraph [012] of the originally-filed specification and original claim 1. Further, in claims 7, 15, and 23, substituents "methyl, ethyl, propyl" for Ar are added, which does not constitute new matter, because the substituents "C1-C10-alkyl," which include "methyl, ethyl, propyl," for Ar are disclosed in paragraphs [015] and [027] of the originally-filed specification.

Therefore, Applicants have not introduced any new matter by the amendments, nor are any estoppels intended thereby.

II. Double Patenting Rejection under 35 U.S.C. § 101

The Examiner provisionally rejects claims 1-8 and 26-28 under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-8 and 27-29 of co-pending Application No. 10/715,358 ("the co-pending '358 application"). Office Action, page 2.

In the co-pending '358 application (Attorney Docket No. 02481.1834-00000), Applicants have canceled claims 1-7 and 27-29 in the Amendment and Reply under 37 C.F.R. § 1.111 filed on the same day of this Amendment and Reply, *i.e.*, February 13, 2006, rendering this rejection of claims 1-7 and 26-28 moot.

Further, Applicants respectfully disagree and traverse the rejection of claim 8 under 35 U.S.C. § 101 as claiming the same invention as that of claim 8 of the co-pending '358 application for at least the following reason.

The M.P.E.P. clearly instructs that "35 U.S.C. 101 prevents two patents from issuing on the same invention. 'Same invention' means identical subject matter." M.P.E.P. § 804 II.A. (citations omitted). Not all compounds recited in claim 8 of the present application are identical to those recited in claim 8 of the co-pending '358 application. Thus, claim 8 of the present application does not claim the same invention as that of claim 8 of the co-pending '358 application. Accordingly, this rejection of claim 8 is improper.

Applicants respectfully request this rejection be withdrawn.

III. Rejection under 35 U.S.C. § 102(b)

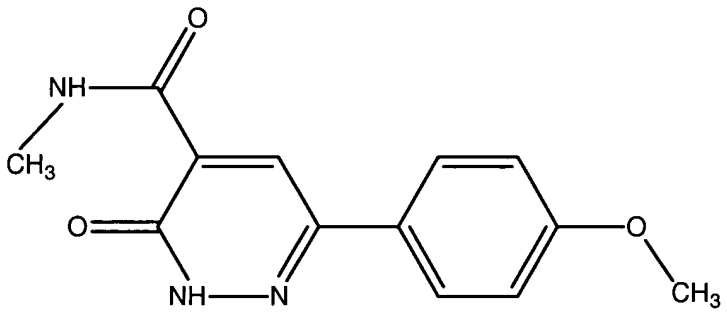
The Examiner rejects claims 1-7, 26, and 27 under 35 U.S.C. § 102(b) as being anticipated by WO 99/44995 to Yoshizaki et al. ("*Yoshizaki*"). Office Action, page 3. Specifically, the Examiner alleges that *Yoshizaki* discloses compound "2,3-dihydro-6-(4-methoxyphenyl)-N-methyl-3-oxo-4-[p]yridazinecarboxamide" which reads on the compound of formula (I) of the present invention, wherein Ar = phenyl substituted with methoxy and A = CONH-methyl. *Id.* Applicants respectfully disagree and traverse this rejection for at least the following reason.

The Examiner has failed to point to the specific location where the compound "2,3-dihydro-6-(4-methoxyphenyl)-N-methyl-3-oxo-4-[p]yridazinecarboxamide" is disclosed in *Yoshizaki*.

Indeed, by reviewing the English abstract of *Yoshizaki*, Applicants respectfully submit that because R3 in formula (1) of *Yoshizaki* is not a hydrogen, the compounds of

formula (1) disclosed in *Yoshizaki* do not include "2,3-dihydro-6-(4-methoxyphenyl)-N-methyl-3-oxo-4-[p]yridazinecarboxamide" as shown in the Office Action at page 3.

Even if, solely for the purpose of argument, the compound "2,3-dihydro-6-(4-methoxyphenyl)-N-methyl-3-oxo-4-[p]yridazinecarboxamide" as shown in the Office Action at page 3 were disclosed in *Yoshizaki*, this compound has been provisoed out from the presently claimed invention by the current amendments in, for example, claim 1, wherein the following compound, which has the same structure as shown in the Office Action at page 3, is provisoed out:



6-(4-methoxyphenyl)-4-methylcarbamoyl-2H-pyridazin-3-one.

Accordingly, this rejection is improper. Applicants respectfully request this rejection be withdrawn.

IV. Rejection under 35 U.S.C. § 112, First Paragraph

The Examiner rejects claims 17-25 under 35 U.S.C. § 112, first paragraph, for lack of enablement. Office Action, page 4. Specifically, the Examiner alleges that "[t]here are compounds that treat a range of cancers, but no one has ever been able to figure out how to get a compound to be effective against cancer generally, or even a

majority of cancers." *Id.* The Examiner further alleges that because "[d]ifferent types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities," "it is beyond the skill of oncologists today to get an agent to be effective against cancers generally." *Id.* Applicants respectfully disagree and traverse this rejection for at least the following reasons.

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." M.P.E.P. § 2164.01. Further, "if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate." *Id.* § 2164.02.

Here, the originally-filed specification clearly indicates that "[i]t is known from literature that in the case of neoplastic diseases such as cancer, there is a connection between the therapy of said diseases and the inhibition of [the kinase] CDK2." Specification, paragraph [004]. Therefore, if a compound shows an inhibitory effect on the kinase CDK2, one of ordinary skill in the art would reasonably believe that it can be used for the treatment of cancer based on the information known in the art.

As shown under "CDK2/Cyclin E Flashplate Assay: 96-well format" in paragraphs [0301]-[0303] of the originally-filed specification, the inventive compounds showed anticancer potency as indicated by the IC_{50} values of inhibiting the kinase CDK2. Therefore, contrary to the Examiner's allegation, the specification has demonstrated that, coupled with the information known in the art, one of ordinary skill in the art would

use the presently claimed compounds for treatment of cancer without undue experimentation.

As the Examiner has failed to point to any evidence rebutting the correlation between the treatment of cancer and the inhibition of the kinase CDK2, this rejection is improper.

In addition, as to claim 25, the Examiner alleges that because the term "tumor" "covers more than just cancers," for example, neoplasms; precancerous conditions, such as lumps, lesions, and polyps; and any kind of swelling arising from inflammation, the specification cannot enable claim 25. *Id.* Applicants respectfully disagree.

However, even, for purpose of argument only, assuming that the Examiner's assertion of the scope of the term "tumor" is correct, claim 25 clearly limits the scope of the tumor to "a solid tumor." Therefore, for this additional reason, this rejection of claim 25 is also improper.

Accordingly, Applicants respectfully request this rejection be withdrawn.

V. Rejection under 35 U.S.C. § 112, Second Paragraph

The Examiner further rejects claims 1-7 and 9-28 under 35 U.S.C. § 112, second paragraph, as being indefinite. Office Action, page 5. Specifically, the Examiner asserts that the phrase "may in turn be" in defining R and Ar in claim 1 does not have a clear meaning. *Id.* at page 6. Applicants respectfully disagree. However, solely for the purpose of advancing the prosecution, Applicants have amended claims 1-7, 9-15, and 17-23 to make it clearer. Therefore, in view of the amendments, this rejection is moot. Applicants respectfully request this rejection be withdrawn.

In addition, the Examiner alleges that "it appears that 'at least monosubstituted is referring to C_1-C_6-alkyl' and not to other definitions of R or Ar." Office Action, page 5. Applicants respectfully disagree.

In claim 1, for example, the term "unsubstituted or at least monosubstituted" defines R or Ar and should be read into all of the radicals which follow the term, *i.e.*, R is unsubstituted or at least monosubstituted C_1-C_{10}-alkyl, unsubstituted or at least monosubstituted aryl, unsubstituted or at least monosubstituted aryl-(C_1-C_{10}-alkyl)-, unsubstituted or at least monosubstituted heteroaryl, unsubstituted or at least monosubstituted heteroaryl-(C_1-C_{10}-alkyl)-, unsubstituted or at least monosubstituted heterocyclyl, unsubstituted or at least monosubstituted heterocyclyl-(C_1-C_{10}-alkyl)-, unsubstituted or at least monosubstituted C_3-C_{10}-cycloalkyl, unsubstituted or at least monosubstituted polycycloalkyl, unsubstituted or at least monosubstituted C_2-C_{10}-alkenyl or unsubstituted or at least monosubstituted C_2-C_{10}-alkinyl; and Ar is unsubstituted or at least monosubstituted aryl or unsubstituted or at least monosubstituted heteroaryl.

Therefore, for the reasons above, Applicants respectfully request this rejection be withdrawn.

VI. Objection

Applicants acknowledge, with appreciation, the indication of allowable subject matter in claim 8, and note that it is objected as based on rejected parent claims. *See* Office Action, page 6. Despite the indication that claim 8 would be allowed if rewritten in independent form, Applicants have decided to keep claim 8 in dependent form for the

reasons discussed above, *i.e.*, that the rejections of claims 1-7 and 9-28 are improper and should be withdrawn. Accordingly, Applicants respectfully request this objection be withdrawn.

VII. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application, and the timely allowance of the pending claims.

If the Examiner believes a telephone conference would be useful in resolving any outstanding issues, the Examiner is invited to call the Applicants' undersigned representative at (202) 408-4218.

If there is any fee due in connection with the filing of this response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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